

EPA Registration File No. 53591-8

PROCESSING REQUEST

Reg # 53591-⁸I

Decision # 514975

Description: New product BASIC CSF 4/26/16

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Julie Breeden-Alemi

Division: RD/IVB 1

Phone: 703-347-0511

Date: 2/13/17



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

53591-8

Date of Issuance:

2/14/17

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Fipronil Technical

Name and Address of Registrant (include ZIP Code):

Carlotta Casalego
Finchimica S.P.A.
Via Lazio, 13
25025 Manerbio (BS) Italy

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Davis, Product Manager 03
Invertebrate & Vertebrate Branch 1, Registration Division
(7505P)

Date:

2/14/17

2. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Fipronil GDCI-129121-1305
 - b. Fipronil GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 53591-8."
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 04/26/2016

If you have any questions, you may contact Julie Breeden-Alemi at 703-347-0511 or via email at Breeden-Alemi.Julie@epa.gov.

Enclosure

ACCEPTED**02/14/2017**Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. **53591-8****FIPRONIL TECHNICAL**

For Manufacturing Use Only

ACTIVE INGREDIENT:

Fipronil: 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-4[(1*R*, *S*)-
(trifluoromethyl)sulfinyl)]-1*H*-pyrazole-3-carbonitrile.....95.4%
OTHER INGREDIENTS:.....4.6%
Total:.....100.0%

KEEP OUT OF REACH OF CHILDREN**WARNING**

FIRST AID	
IF SWALLOWED:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor.• Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15 – 20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378.	
NOTE TO PHYSICIAN	
There is no specific antidote. All treatment should be based on observed signs and symptoms of distress in the patient. Overexposure to materials other than this product may have occurred. In severe cases of overexposure by oral ingestion, lethargy, muscle tremors, and in extreme cases, possible convulsions, may occur.	

See Additional Precautions on Side Panel

Manufactured by:
Finchimica S.p.A.
Via Lazio, 13
25025 Manerbio (BS)
Italy

EPA FILE SYMBOL 53591-I

EPA EST. NO. _____

NET CONTENTS:

LOT NO.:

Fipronil Technical
2/2/2017

Page 1 of 3

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: May be fatal if swallowed, absorbed through skin or inhaled. Causes moderate eye irritation. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear a NIOSH approved particulate respirator with any N, R, or P filter with NIOSH approval number Prefix TC-84A or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C. Wear protective eyewear if appropriate. Wear protective clothing if appropriate.

ENVIRONMENTAL HAZARDS

This product is toxic to birds, fish, estuarine, and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA. Do not contaminate water when disposing of equipment wastewater.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

ONLY FOR MANUFACTURING OR FORMULATION INTO INSECTICIDES/MITICIDES FOR THE FOLLOWING USES:

- Residential indoor (companion animals).
- Uses for which USEPA has accepted the required data/or citations of data the formulator has submitted in support of registration.
- Uses for experimental or emergency purposes in compliance with USEPA requirements.

This product may be used to formulate products for any additional uses not listed on the technical label if the formulator, user group, or grower has complied with USEPA data submission requirements regarding the support of such uses. Each formulator is responsible for obtaining USEPA registration for their end-use product(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store this product in original container, out of reach of children and animals.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Handling:

[*Non-refillable Bags:*] Nonrefillable container. Do not reuse or refill this container. Completely empty bag into application equipment, then dispose of empty bag in a sanitary landfill or by incineration, or by other procedures approved by state and local authorities, Offer for recycling or reconditioning, if available.

[*Non-refillable Drums with Liners:*] Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosed clinging particles. Empty residue into processing equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. Offer the drum for recycling, if available.

[*Non-refillable Plastic Containers or Drums:*] Nonrefillable container. Do not reuse or refill this container. Triple rinse or pressure rinse container (or equivalent) promptly after emptying and offer for recycling (or reconditioning) if available. If recycling or reconditioning is not available, puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

LIMITATIONS OF LIABILITY AND DAMAGES

To the extent consistent with applicable law, the liability of Finchimica S.P.A. and any other seller for any loss or injury, whether based on negligence, breach of warranty, strict liability in tort, or any other cause of action, shall be limited to the purchase price of the product. Prompt notice of any claim must be given by the buyer to Finchimica S.P.A. within ninety days after the application of the product or ninety days after the first planting, whichever is later. Notify Finchimica S.P.A. at this address: Finchimica S.P.A. Via Lazio, 13, 25025 Manerbio (BS), ITA, ITALY.

To the extent consistent with applicable law, Finchimica S.P.A. and any other seller of the product shall not be liable, and any and all claims against Finchimica S.P.A. and any other seller are waived, for special, indirect, incidental, or consequential damages or expenses of any nature, including, but not limited to, loss of profits or income, and crop or property loss or damage, whether or not based on negligence, breach of warranty, strict liability in tort or any other cause of action.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, FINCHIMICA S.P.A. OFFERS THIS PRODUCT AND THE BUYER AND USER ACCEPT IT SUBJECT TO THE FOREGOING CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY, LIABILITY AND DAMAGES, WHICH MAY BE VARIED ONLY BY AGREEMENT IN WRITING SIGNED BY A DULY AUTHORIZED REPRESENTATIVE OF FINCHIMICA S.P.A.

Breeden-Alemi, Julie

From: Waleko, Garland
Sent: Monday, January 30, 2017 1:23 PM
To: Breeden-Alemi, Julie
Cc: Conde, Rosaura; Costello, Kevin
Subject: FW: GDCI/EDSP Fipronil

DCT/S

Hi Julie, re your email today, see below – status is the same. Rosaura (copied here) will be taking fipronil while I am on detail in EFED.

Thanks!
Garland

From: Waleko, Garland
Sent: Tuesday, September 27, 2016 1:31 PM
To: Breeden-Alemi, Julie Breeden-Alemi.Julie@epa.gov
Subject: RE: GDCI/EDSP Fipronil

Hi Julie,

Yes -129121-1305 still has outstanding studies, and 129121-1512 is outstanding. No EDSP DCI's.

Thanks!
Garland

From: Breeden-Alemi, Julie
Sent: Tuesday, September 27, 2016 6:58 AM
To: Britton, Cathryn <Britton.Cathryn@epa.gov>
Subject: GDCI/EDSP Fipronil

Good morning Cathryn!

I have a PRIA due date next for which I need the current outstanding info for Fipronil. The last I checked the following were outstanding:

GDCI: 129121-1305 and 129121-152

Is this still correct? Any EDSPs?

Thank you so much.
Have a wonderful day,
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

Breeden-Alemi, Julie

From: Ana Koster <alkoster@lewisharrison.com>
Sent: Monday, February 13, 2017 1:04 PM
To: Breeden-Alemi, Julie
Cc: Davis, Kable; IVB1; David Lewis
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I
Attachments: 53591-I_FipronilTechnical_EPAREgistration_CWRTCOD_Revised_20170213.pdf

Hi Amy,

Attached please find the form. Let me know if you need anything else.

Thanks for all your help!

Best,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
Office phone#: 202-393-3903 x.117 (W)
f. 202-393-3906
alkoster@lewisharrison.com

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From: Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]
Sent: Monday, February 13, 2017 12:51 PM
To: David Lewis; Ana Koster; Eliot Harrison
Cc: Davis, Kable; IVB1
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Oops... What I meant to say was "where the DATE on the form matches the date on the revised matrix." My apologies for the typo!

Julie

From: Breeden-Alemi, Julie
Sent: Monday, February 13, 2017 12:39 PM
To: David Lewis <dlewis@lewisharrison.com>; Ana Koster <alkoster@lewisharrison.com>; Eliot Harrison <eharrison@lewisharrison.com>
Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Hi David,

The matrix looks good, thank you for your expedient efforts! We need a revised Certification with respect to Citation of Data form (EPA form 8570-34) where the data on the form matches the date on the revised data matrix. If you can send this form today, we will be in good shape.

Many thanks,

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Davis, Kable
Sent: Monday, February 13, 2017 12:08 PM
To: David Lewis <dlewis@lewisharrison.com>; Ana Koster <alkoster@lewisharrison.com>; Eliot Harrison <eharrison@lewisharrison.com>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Received. Thanks for sending, David.

From: David Lewis [<mailto:dlewis@lewisharrison.com>]
Sent: Monday, February 13, 2017 12:05 PM
To: Davis, Kable <Davis.Kable@epa.gov>; Ana Koster <alkoster@lewisharrison.com>; Eliot Harrison <eharrison@lewisharrison.com>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Results

Hi Bo,

Attached are three files – a revised EPA data matrix (track changes), a revised EPA data matrix (clean), and a revised public version of the data matrix. I believe that we caught all of the misplacements, or missing MRID Nos., but if you or Julie spot anything we missed, please let us know.

Thanks,
David

E. David Lewis
Lewis & Harrison
(202) 393-3903, ext. 112
<https://lewisharrison.com/>

From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: Monday, February 13, 2017 11:25 AM
To: David Lewis; Ana Koster; Eliot Harrison
Cc: Breeden-Alemi, Julie
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Perfect. Thank you!

From: David Lewis [mailto:dlewis@lewisharrison.com]
Sent: Monday, February 13, 2017 11:14 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Ana Koster <alkoster@lewisharrison.com>; Eliot Harrison <eharrison@lewisharrison.com>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Will do. We should have it to you by noon. Just doing some last minute checks on a few that do not show up in PDMS.

-D

From: Davis, Kable [mailto:Davis.Kable@epa.gov]
Sent: Monday, February 13, 2017 10:58 AM
To: David Lewis; Ana Koster; Eliot Harrison
Cc: Breeden-Alemi, Julie
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Having both would speed up our review. Thanks for asking.

From: David Lewis [mailto:dlewis@lewisharrison.com]
Sent: Monday, February 13, 2017 10:57 AM
To: Davis, Kable <Davis.Kable@epa.gov>; Ana Koster <alkoster@lewisharrison.com>; Eliot Harrison <eharrison@lewisharrison.com>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Hi Bo,

Do you or Julie need/want a track changes version as well as a clean version of the revised matrix?

Thanks,
David

E. David Lewis
Lewis & Harrison
(202) 393-3903, ext. 112
<https://lewisharrison.com/>

From: Davis, Kable [mailto:Davis.Kable@epa.gov]
Sent: Monday, February 13, 2017 9:29 AM
To: Ana Koster; David Lewis; Eliot Harrison
Cc: Breeden-Alemi, Julie
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Feel better, Ana.

From: Ana Koster [mailto:alkoster@lewisharrison.com]
Sent: Monday, February 13, 2017 8:52 AM

To: David Lewis <dlewis@lewisharrison.com>; Davis, Kable <Davis.Kable@epa.gov>; Eliot Harrison <eharrison@lewisharrison.com>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Hi David, Bo-

Davis is correct: All of the MRIDs came out of the Registration Review scoping documents.

David: I'm almost recovered from the flu and I'm working today. Let me know if I can help out with anything.

Thanks,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
Office phone#: 202-393-3903 x.117 (W)
f. 202-393-3906
alkoster@lewisharrison.com

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From: David Lewis
Sent: Monday, February 13, 2017 8:50 AM
To: Davis, Kable; Eliot Harrison
Cc: Breeden-Alemi, Julie; Ana Koster
Subject: RE: Data Matrix Issues; EPA File Symbol 53591-I

Hi Bo,

Ana has been out with a bad case of the flu. I'll work on it this morning. My recollection is that Ana got most of the MRID Nos. from the RED & Registration Review Documents, along with some of the more current MRIDs (e.g., data required from the GDCI) from PDMS. I will try to get back to you by early afternoon with an indication as to how Finchimica wants to proceed. While I can understand the advantage of shifting to cite-all the current intent is to remain with the selective method.

Working under the assumption that Finchimica wants to remain with selective, let me know if responding early this afternoon with a revised matrix (or an extension, if questions remain) is still workable with respect to the PRIA deadline. If it is not, give me a call and we can discuss how much time would be needed.

Thanks,
David

E. David Lewis
Lewis & Harrison
(202) 393-3903, ext. 112

<https://lewisharrison.com/>

From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: Monday, February 13, 2017 8:31 AM
To: David Lewis; Eliot Harrison
Cc: Breeden-Alemi, Julie
Subject: FW: Data Matrix Issues; EPA File Symbol 53591-I

Hi David and Eliot –

I received an out of office reply from Ana in response to my email below. Is this something one of you can work on? Unfortunately, it's rather time sensitive. The data matrix that was submitted had multiple errors throughout the document. Some of the referenced citations were for other studies, while others were not in our system at all. Do you want to take a second attempt at doing a selective citation or do you want to switch over to a cite-all for generic data? The second option will help prevent the need for a renegotiation, however it is totally up to you.

Enjoy the day.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Davis, Kable
Sent: Monday, February 13, 2017 8:24 AM
To: 'Ana Koster' <alkoster@lewisharrison.com>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: Data Matrix Issues; EPA File Symbol 53591-I

Hi Ana –

I hope you had a nice weekend. In review of the data matrix submitted for EPA File Symbol 53591-I, we've noticed multiple errors. Some of the MRID numbers referenced are for the wrong study, while others are not in our system at all. Unfortunately, the predecisional due date is tomorrow. Do you want to take another try at doing a selective citation or do you want to switch over the a cite-all for generic data? The second option is the easiest and quickest way to have this product registered. We will need a new data matrix by noon tomorrow. This will give us time to review it by COB tomorrow. If it is still unacceptable, we will need to discuss the possibility of extending the due date so we can have time to adequately fix the data matrix.

I hope all is well.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

Breeden-Alemi, Julie

From: Ana Koster <alkoster@lewisharrison.com>
Sent: Thursday, February 02, 2017 10:16 AM
To: Breeden-Alemi, Julie
Cc: Davis, Kable
Subject: RE: Voice Message: EPA File Symbol 53591-I
Attachments: 053591-xxxxI.20170131.FipronilTechnical.NewRegistration.CWRTCOD.pdf; 053591-xxxxI.20170202.FipronilTechnical.NewRegistration.Label.pdf

Hi Julie,

Sorry about the typo.

Attached is a clean copy of the revised label with the typo corrected. I'm also attaching a new Certification with Respect to Citation of Data form that reflects the date of the revised data matrix.

Let me know if you have any questions and thanks for all of you help!

Best,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
Office phone#: 202-393-3903 x.117 (W)
f. 202-393-3906
alkoster@lewisharrison.com

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From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: Wednesday, February 01, 2017 3:48 PM
To: Ana Koster
Cc: Davis, Kable
Subject: RE: Voice Message: EPA File Symbol 53591-I

Hi Ana,

This is great! There is only one quick revision that is necessary on page 3: "...absorbed through or inhaled" needs to have the word "skin" inserted to read "...absorbed through skin or inhaled." See the attached document for clarification if needed. You can simply send a clean copy of the revised label this time!

We also need a revised Certification with Respect to Citation of Data form such that the date on that form matches the date on the recently submitted revised data matrix dated 1/31/17.

Thank you and enjoy the afternoon!
Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Ana Koster [<mailto:alkoster@lewisharrison.com>]
Sent: Wednesday, February 01, 2017 12:04 PM
To: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Cc: Davis, Kable <Davis.Kable@epa.gov>
Subject: RE: Voice Message: EPA File Symbol 53591-I

Resub

Hi Julie,

Thanks for getting back to me so quickly regarding the label.

Attached please find a revised version of the label (highlighted and non-highlighted versions) for your review. The revised label has been modified to comply with all of your requests, except for the last one regarding the sentence "which may be varied only by agreement in writing" in the warranty statement. Please note that we respectfully disagree with the Agency's finding that this language "could imply that the consumer can use the product in ways not consistent with the label, if it is agreed upon in writing." This language is specific to the limitations/terms of the warranty (as it is noted prior to the language in question), which may only be varied in agreement in writing between the parties. There are also other competitor's labels, which the Agency has approved with similar language (see EPA Reg. No. 7969-351, and EPA Reg. No. 7969-243).

Thanks for all of your assistance with this registration action and let me know if you have any further questions or concerns.

Best,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
Office phone#: 202-393-3903 x.117 (W)
f. 202-393-3906
alkoster@lewisharrison.com

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From: Breeden-Alemi, Julie [<mailto:Breeden-Alemi.Julie@epa.gov>]
Sent: Tuesday, January 31, 2017 12:59 PM
To: Ana Koster
Cc: Davis, Kable
Subject: RE: Voice Message: EPA File Symbol 53591-I

Hi Ana,

Please find attached initial label comments for File Symbol No. 53591-I. The product chemistry review should be completed in the next few days, and there could be additional comments, but the Pre-Decisional date is coming up 2/14/17, and it will serve us well to go ahead with the label revision at this point. Please revise and send both clean and highlighted/tracked changes in electronic readable pdf form.

Let me know if you have any questions,

Many thanks,

Julie

Julie A. Breeden-Alemi, DVM
U.S. Environmental Protection Agency
OCSPP / OPP / RD / IVB1
Breeden-Alemi.Julie@epa.gov
Phone: 703.347.0511

From: Ana Koster [<mailto:alkoster@lewisharrison.com>]
Sent: Tuesday, January 31, 2017 10:36 AM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Voice Message

Rec'd

Hi Bo, Julie-

Attached please find the revised proposed label (highlighted and non-highlighted versions) and data matrices (Agency and Public copies) for Fipronil Technical (EPA File Symbol 53591-I) for your review.

Thank you for all of your assistance with this registration action and let me know if you have any questions.

Best,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
Office phone#: 202-393-3903 x.117 (W)
f. 202-393-3906
alkoster@lewisharrison.com

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From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: Monday, January 30, 2017 3:56 PM

To: Ana Koster
Cc: Breeden-Alemi, Julie
Subject: RE: Voice Message

Great – thanks, Ana.

From: Ana Koster [mailto:alkoster@lewisharrison.com]
Sent: Monday, January 30, 2017 3:05 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Voice Message

Hi Bo,

Sorry for the late response. It's been a bit hectic around here these past few weeks.

To answer your question, Finchimica would like to limit the use of their product for the formulation of insecticides to be used for companion animal treatments only. I'm in the process of revising the proposed label and data matrix and should be sending the revised documents to you and Julie sometime tomorrow.

Thanks,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
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Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
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From: Davis, Kable [mailto:Davis.Kable@epa.gov]
Sent: Monday, January 30, 2017 12:50 PM
To: Ana Koster
Cc: Breeden-Alemi, Julie
Subject: RE: Voice Message

Hi Ana –

I hope you had a nice weekend. Please see my email below concerning EPA File Symbol 53591-I. Since the predecisional due date is quickly approaching (2/14/17), we need to know if you are wanting to delete some of the uses from the label. Would you mind sending me an email confirming if you want to keep all of the uses that were submitted? If so, we should be able to register the product very soon. If not, we need updated versions of the label and data compensation forms sent to us ASAP so we can review them.

Enjoy the day.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

From: Davis, Kable
Sent: Thursday, January 26, 2017 1:39 PM
To: 'Ana Koster' <alkoster@lewisharrison.com>
Subject: Voice Message

Hi Ana –

Thanks for the voice message. If I'm understanding the situation correctly, you are wanting to delete all of the uses, except for applications to domestic animals. Would you mind emailing me your question and I'll do some digging and will get back with you.

Hope all is well.
Bo

Kable Bo Davis
Product Manager 3
Invertebrate & Vertebrate Branch 1
(703) 306-0415
davis.kable@epa.gov

Breeden-Alemi, Julie

From: Ana Koster <alkoster@lewisharrison.com>
Sent: Tuesday, January 31, 2017 10:36 AM
To: Davis, Kable
Cc: Breeden-Alemi, Julie
Subject: RE: Voice Message
Attachments: 053591-xxxxI.20170131.FipronilTechnical.NewRegistration.DM.Agency.pdf; 053591-xxxxI.20170131.FipronilTechnical.NewRegistration.DM.Public.pdf; 053591-xxxxI.20170131.FipronilTechnical.NewRegistration.Label.Highlighted.pdf; 053591-xxxxI.20170131.FipronilTechnical.NewRegistration.Label.Nonhighlighted.pdf

Hi Bo, Julie-

Attached please find the revised proposed label (highlighted and non-highlighted versions) and data matrices (Agency and Public copies) for Fipronil Technical (EPA File Symbol 53591-I) for your review.

Thank you for all of your assistance with this registration action and let me know if you have any questions.

Best,

Ana Rodriguez-Koster
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From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: Monday, January 30, 2017 3:56 PM
To: Ana Koster
Cc: Breeden-Alemi, Julie
Subject: RE: Voice Message

Great – thanks, Ana.

From: Ana Koster [<mailto:alkoster@lewisharrison.com>]
Sent: Monday, January 30, 2017 3:05 PM
To: Davis, Kable <Davis.Kable@epa.gov>
Cc: Breeden-Alemi, Julie <Breeden-Alemi.Julie@epa.gov>
Subject: RE: Voice Message

Hi Bo,

Sorry for the late response. It's been a bit hectic around here these past few weeks.

To answer your question, Finchimica would like to limit the use of their product for the formulation of insecticides to be used for companion animal treatments only. I'm in the process of revising the proposed label and data matrix and should be sending the revised documents to you and Julie sometime tomorrow.

Thanks,

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From: Davis, Kable [<mailto:Davis.Kable@epa.gov>]
Sent: Monday, January 30, 2017 12:50 PM
To: Ana Koster
Cc: Breeden-Alemi, Julie
Subject: RE: Voice Message

Hi Ana –

I hope you had a nice weekend. Please see my email below concerning EPA File Symbol 53591-I. Since the predecisional due date is quickly approaching (2/14/17), we need to know if you are wanting to delete some of the uses from the label. Would you mind sending me an email confirming if you want to keep all of the uses that were submitted? If so, we should be able to register the product very soon. If not, we need updated versions of the label and data compensation forms sent to us ASAP so we can review them.

Enjoy the day.
Bo

Kable Bo Davis
Product Manager 3
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(703) 306-0415
davis.kable@epa.gov

From: Davis, Kable
Sent: Thursday, January 26, 2017 1:39 PM
To: 'Ana Koster' <alkoster@lewisharrison.com>
Subject: Voice Message

Hi Ana –

Thanks for the voice message. If I'm understanding the situation correctly, you are wanting to delete all of the uses, except for applications to domestic animals. Would you mind emailing me your question and I'll do some digging and will get back with you.

Hope all is well.

Bo

Kable Bo Davis

Product Manager 3

Invertebrate & Vertebrate Branch 1

(703) 306-0415

davis.kable@epa.gov

Breeden, Julie

From: Ana Koster <alkoster@lewisharrison.com>
Sent: Tuesday, April 26, 2016 11:47 AM *Resubmission*
To: Breeden, Julie
Cc: Davis, Kable; IVB1
Subject: RE: File Symbol No. 53591-I
Attachments: 053591-xxxxl.20160426.FipronilTechnical.EPARegistration.CSF.Basic.Revised.v2.pdf

Hi Julie,

Attached is the revised CSF that includes the chemical names for each ingredient. Note that, for consistency, I copied the chemical names as they appear in the submitted 5-batch study. Let me know if you have any other question.

Thanks,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
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From: Ana Koster
Sent: Tuesday, April 26, 2016 9:56 AM
To: 'Breeden, Julie'
Cc: Davis, Kable; IVB1
Subject: RE: File Symbol No. 53591-I

Ok. Thanks. I'll work on those changes this morning and send back to you.

Best,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
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From: Breeden, Julie [<mailto:Breeden.Julie@epa.gov>]

Sent: Tuesday, April 26, 2016 9:55 AM

To: Ana Koster

Cc: Davis, Kable; IVB1

Subject: RE: File Symbol No. 53591-I

Good morning Ana,

The change you made is good. The only other change that needs to be made is to add the chemical names for each entry in box 10... a random example of a chemical name would look like this: N-[1-[(6-chloropyridin-3-yl)methyl]-4,5-dihydroimidazol-2-yl]nitramide

Thanks so much!

Julie

Julie A. Breeden, DVM

U.S. Environmental Protection Agency

OCSPP / OPP / RD / IVB1

Breeden.Julie@epa.gov

Phone: 703.347.0511

From: Ana Koster [<mailto:alkoster@lewisharrison.com>]

Sent: Tuesday, April 26, 2016 7:22 AM

To: Breeden, Julie <Breeden.Julie@epa.gov>

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>

Subject: RE: File Symbol No. 53591-I

Resubmission

Hi Julie,

Thanks for clarifying. Now I get it.

Attached please find a revised basic CSF, which I updated per your comments. Please review and let me know if it's okay or if I should make any other change.

Thanks,

Ana Rodriguez-Koster

Senior Associate & Team Lead, Caribbean & Latin America

Lewis & Harrison, LLC

122 C Street NW, Suite 505

Washington, DC 20001

Home office phone#: 410-696-2236 (M, T, R, F)

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alkoster@lewisharrison.com

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From: Breeden, Julie [<mailto:Breeden.Julie@epa.gov>]

Sent: Monday, April 25, 2016 3:15 PM

To: Ana Koster

Cc: Davis, Kable; IVB1

Subject: RE: File Symbol No. 53591-I

Hi Ana,

Yes, those are the documents that are currently under action. The CSF was submitted for review, and the technical screen came back with deficiencies that need to be addressed before the action can proceed. Please take a look at the technical screen that I attached in the previous email dated today. It explains the deficiencies. I expanded on one of them in the email. These appear to be additional deficiencies or deficiencies that need re-addressing.

Let me know if you'd like to speak via phone. We can talk right now or set a time tomorrow.

Julie

Julie A. Breeden, DVM

U.S. Environmental Protection Agency

OCSPP / OPP / RD / IVB1

Breeden.Julie@epa.gov

Phone: 703.347.0511

From: Ana Koster [<mailto:alkoster@lewisharrison.com>]

Sent: Monday, April 25, 2016 3:03 PM

To: Breeden, Julie <Breeden.Julie@epa.gov>

Cc: Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>

Subject: RE: File Symbol No. 53591-I

Hi Julie,

It's good to hear from you again. Hope you also had a great weekend.

Regarding the CSF deficiency, please note that we did respond to John Redden on 4/7/2016 and provided a revised CSF. Attached is a copy of the correspondence. Please review and let me know if there are any questions.

Thanks,

Ana Rodriguez-Koster

Senior Associate & Team Lead, Caribbean & Latin America

Lewis & Harrison, LLC

122 C Street NW, Suite 505

Washington, DC 20001



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D433072; **FILE SYMBOL No.:** 53591-I (screen); **PRODUCT NAME:** Fipronil Technical;
DECISION No.: 514975; **PC Code(s):** 129121; **ACTION CODE:** R334; **FOOD Use:** No

DATE OUT: April 25, 2016

SUBJECT: 45/90 day screen results for technical product "Fipronil Technical"

FROM: Shyam Mathur, Product Chemistry Team Leader CITAB/RD (7505P)

TO: Julie Breeden / Kable Davis, RM 03, I-V Branch 1 / RD (7505P)

Company Name: Finchimica S.p.A

Active Ingredient(s): Fipronil (95.4%)

MRID No(s): 49829501 to -14

CONCLUSION:

Deficiencies: Yes

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

Group A: All required data submitted

Group B: All required data submitted.

CSF: Basic CSF (dated 04-07-2016) submitted.

Note 1: The proposed CSF must be revised to include the chemical names and CAS Nos. of the impurities listed on the CSF.

DRAFT PRODUCT LABEL: Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to the author of this report the corrected deficiencies in response to 10 day letter. The corrected deficiencies will be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

12/APR/2016

SIMILARITY CLINIC MEMORANDUM

Subject: Name of Pesticide Product: Fipronil Technical
EPA Reg. No. /File Symbol: 53591-I
DP Barcode: D432492
Decision No: 514975
Action Code: R334
PC Code: 029806 (fipronil)

From: Eugenia McAndrew, Biologist *Eugenia McAndrew*

Through: John C. Redden, M.S., Senior Risk Assessor *JCR*
Chemistry, Inerts and Toxicology Assessment Branch
Registration Division (7505P)

To: Kable Davis, Risk Manager Team 03
Invertebrate and Vertebrate Branch 1
Registration Division (7505P)

Applicant: Finchimica S.p.A.
Via Lazio, 13
26025 Manerbio (BS)
Italy

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Fipronil	95.4
Other ingredients:	<u>4.6</u>
Total:	100.0

ACTION REQUESTED: Similarity determination for 53591-I, proposed product, and 11678-75, cited product.

BACKGROUND: Finchimica S.p.A. has applied for registration of Fipronil Technical, EPA File Symbol 53591-I, claiming to be substantially similar to Fipronil Technical, EPA Reg. No. 11678-75 (transferred from 74054-5). Both products are technical grade for manufacturing use only. The submission includes a basic CSF dated April 7, 2016, label, data matrix and company letter.

The registrant is using the selective method of data support to satisfy the acute toxicity data requirements. The data matrix cites acute oral (MRID 42918628), acute dermal (MRIDs 42918629 and 42918630), acute inhalation (MRID 43544401), primary eye irritation (MRID 42918632), primary dermal irritation (MRID 42918633) and dermal sensitization (MRID 42918634) studies. All of the studies were conducted on technical fipronil. A search of the OPP electronic databases shows that the acute oral, acute dermal, primary eye irritation, primary skin irritation and dermal sensitization studies were reviewed in a Health Effects Division memo (Dobozy, V.; D197450; PC Code 129121; TXR 0011025; memo date June 7, 1994). The dermal sensitization study was upgraded to acceptable in a follow-up HED memo (Dobozy, V.; D208956; PC Code 129121; TXR 0011366; memo date December 20, 1994). The acute inhalation toxicity study was reviewed in another HED memo (Ioannou, Y.; D211468, D211202, D212067; PC Code 129121; TXR 011425; memo date February 27, 1995).

RECOMMENDATIONS:

1. We compared the basic CSFs and labels of the proposed product, 53591-I, and the cited product, 11678-75, and determined that the two products are substantially similar. The cited acute toxicity data may be used to support this registration.
2. The acute toxicity profile for the proposed product, Fipronil Technical, EPA File Symbol 53591-I, is as follows:

acute oral toxicity	II	cited	MRID 42918628
acute dermal toxicity	III	cited	MRID 42918629
acute dermal toxicity	II*	cited	MRID 42918630
acute inhalation toxicity	II	cited	MRID 43544401
primary eye irritation	III	cited	MRID 42918632
primary skin irritation	IV	cited	MRID 42918633
dermal sensitization	negative	cited	MRID 42918634

*Two dermal toxicity studies are cited on the data matrix. We will use the more conservative study for determining the acute toxicity profile of the product.

3. The proposed basic CSF submitted for 53591-I must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

PRODUCT ID #: 053591-00008

PRODUCT NAME: Fipronil Technical

PRECAUTIONARY STATEMENTS

SIGNAL WORD: WARNING

Hazards to Humans and Domestic Animals:

May be fatal if swallowed, absorbed through skin or inhaled. Causes moderate eye irritation. Do not get in eyes, on skin, or on clothing. Do not breathe spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear a NIOSH approved particulate respirator with any N, R or P filter with NIOSH approval number Prefix TC-84A or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number prefix TC-21C. Wear protective eyewear if appropriate. Wear protective clothing if appropriate.

First Aid:

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

 EPA United States Environmental Protection Agency Washington, DC 20460	<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number
--	--	-----------------------

Application for Pesticide - Section I

1. Company/Product Number 53591-	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Fipronil Technical	PM# Team 10	
5. Name and Address of Applicant (Include ZIP Code) Finchimica S.P.A. Via Lazio, 13 25025 Manerbio (BS) Italy <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>11678-75</u> Product Name: <u>MCW 437 Technical</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below
---	--

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Registration Service Fee

Fee Category R334: New Product; MUP or End Use Product with Unregistered Source of the Active Ingredient; Selective Data Citation

Fee = \$19,838.00; Review Time = 11 months

For questions, contact Ana Koster at 202-393-3903 x. 117 or at alkoster@lewisharrison.com

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No *Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify): <u>Fiber Drums with Steel Lock-Tops</u>
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 15 gal.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Ana Rodriguez-Koster, Lewis & Harrison, LLC, 122 C Street NW, Ste. 505, Washington, DC 20001		Title Agent	Telephone No. (Include Area Code) 202-393-3903 x. 117
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Agent		
4. Typed Name Ana Rodriguez-Koster	5. Date 3/10/2016		

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W. Suite 505
Washington, DC 20001
telephone 202.393.3903
fax 202.393.3906

March 10, 2016

VIA ELECTRONIC SUBMISSION (EPA CDX)

Document Processing Desk [APPL]
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTENTION: Richard Gebken
Product Manager, Team 10

SUBJECT: Fipronil Technical (EPA Reg. No. 53591__)
Application for Registration of a New Technical Grade Active Ingredient
PRIA Category R224 (New Manufacturing Use, Old A.I., Selective Method)
Electronic Submission

Dear Mr. Gebken:

On behalf of Finchimica S.p.A. ("Finchimica"), I am submitting an application to register their Technical Grade Active Ingredient (TGA), **Fipronil Technical**. **Fipronil Technical** contains 95.4% fipronil as its active ingredient and is intended for use in the formulation of non-food use (end-use) insecticides.

A) SIMILARITY TO REGISTERED PRODUCT:

Fipronil Technical is similar in use and composition to the registered ADAMA product, MCW 437 Technical (EPA Reg. No. 11678-75). The proposed label for **Fipronil Technical** is essentially identical to the label for MCW 437 Technical (EPA Reg. No. 11678-75). All precautionary statements, first aid language, use sites, and use directions are consistent with the language listed on the MCW 437 Technical (EPA Reg. No. 11678-75) label.

B) DATA REQUIREMENTS:

Enclosed please find product-specific chemistry data for **Fipronil Technical**. To fulfill the remaining data requirements, Finchimica is relying on the "selective method" of data support and providing a Data Matrix, which lists appropriate citations of studies on file with the Agency that have been evaluated as part of the Registration Review initiative for Fipronil.

C) REGISTRATION FEES:

This application involves the registration of a new technical grade product with an old active ingredient. As such, it falls into the R334 category, with a review timeline of 11 months and a fee-for-service charge of \$19,838.00. Note that I submitted electronic payment to the Agency on 2/4/2016. Attached I am including proof of payment for your reference.

Fipronil Technical (EPA Reg. No. 53591__)
Application for Registration of a New Technical Grade Active Ingredient
PRIA Category R224 (New Manufacturing Use, Old A.I., Selective Method)
Electronic Submission

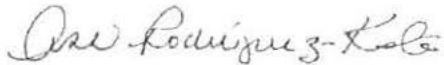
D) SUPPORTING DOCUMENTS:

Enclosed please find the following documents in support of the registration for **Fipronil Technical**:

1. Application for Pesticide Registration Form;
2. Confidential Statement of Formula for one (1) Basic Formulation;
3. Certification with Respect to Citation of Data Form;
4. Data Matrix Form (confidential and non-confidential versions);
5. Proposed Product Label;
6. Product Chemistry Data;
7. Justification for Non-Applicable Data Requirements Volume;
8. Transmittal Document; and,
9. Proof of PRIA payment.

Thank you for your assistance with this application. If you have any questions about this submission, please call me at 202-393-3903 ext. 117 or e-mail me at alkoster@lewisharrison.com.

Sincerely,



Ana Rodriguez-Koster
Agent for,
Finchimica S.p.A.

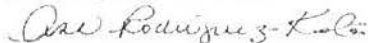
Enclosures

cc: Carlotta Casalego, Finchimica S.p.A.

EPA TRANSMITTAL DOCUMENT

SUBMISSION DATED:	3/10/2016
STUDY SUBMITTER:	Finchimica S.p.A. Via Lazio, 13 25025 Manerbio (BS) Italy
SUBMITTED IN SUPPORT OF:	Fipronil Technical
EPA REGISTRATION NO.:	53591-__
REGULATORY ACTION:	Application for Pesticide Registration
STUDIES SUBMITTED:	
	<u>Fipronil Technical: Product Identity and Composition, Beginning Materials, Production Process, and Formation of Impurities (March 10, 2016) by Lewis & Harrison, LLC; 9 pages with a 38-page Confidential Appendix.</u> <i>US EPA Guidelines: 830.1550 - 830.1670</i>
	MRID Number: 49829501
	<u>Fipronil: HPLC/MS/DAD Screening of Five Batches (June 9, 2014) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 149/2013; 6 pages with a 153-page Confidential Appendix.</u> <i>US EPA Guideline: 830.1700</i>
	MRID Number: 49829502
	<u>Fipronil: Complete Analysis of Five Batch Samples (June 9, 2014) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 133/2013; 5 pages with a 95-page Confidential Appendix.</u> <i>US EPA Guideline: 830.1700</i>
	MRID Number: 49829503
	<u>Fipronil: Validation of the Analytical Method for the Determination of the Active Ingredient Content (June 9, 2014) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 131/2013; 15 pages with a 41-page Confidential Appendix.</u> <i>US EPA Guideline: 830.1800</i>
	MRID Number: 49829504

	<p><u>Fipronil: Validation of the Analytical Method for the Determination of the Significant Impurities Content</u> (June 17, 2014) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 132/2013; 7 pages with a 120-page Confidential Appendix.</p> <p><i>US EPA Guideline: 830.1800</i></p>
	MRID Number: 49829505
	<p><u>Fipronil Technical: Physical and Chemical Characteristics</u> (December 4, 2015) by Finchimica S.p.A.; 6 pages with a 3-page Confidential Appendix.</p> <p><i>US EPA Guidelines: 830.6302, 830.6303, 830.6304</i></p>
	MRID Number: 49829506
	<p><u>Fipronil Technical: Determination of the Accelerated Storage Stability and Corrosion Characteristics</u> (July 2, 2015) by S. Nichetti, ChemService S.r.l. Controlli e Ricerche; Study No. 276/2015; 75 pages with a 3-page Confidential Appendix.</p> <p><i>US EPA Guidelines: 830.6313, 830.6317, 830.6320</i></p>
	MRID Number: 49829507
	<p><u>Fipronil Technical: Non-Applicable Data Requirements</u> (March 10, 2016) by Lewis & Harrison, LLC; 6 pages.</p> <p><i>US EPA Guidelines: 830.6314, 830.6315, 830.6316, 830.6319, 830.6321, 830.7000, 830.7100, 830.7220, 830.7370, 830.7520</i></p>
	MRID Number: 49829508
	<p><u>Fipronil: Spectroscopic Characterization of Five Batch Samples</u> (October 7, 2013) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 134/2013; 18 pages with a 35-page Confidential Appendix.</p> <p><i>US EPA Guideline: 830.7050</i></p>
	MRID Number: 49829509
	<p><u>Fipronil: Determination of the Melting Point</u> (October 4, 2013) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 127/2013; 18 pages with a 4-page Confidential Appendix.</p> <p><i>US EPA Guideline: 830.7200</i></p>
	MRID Number: 49829510
	<p><u>Fipronil Technical: Determination of the Relative Density</u> (July 2, 2015) by S. Nichetti, ChemService S.r.l. Controlli e Ricerche; Study No. 275/2015; 17 pages with a 3-page Confidential Appendix.</p> <p><i>US EPA Guideline: 830.7300</i></p>
	MRID Number: 49829511
	<p><u>Fipronil: Determination of the Partition Coefficient (n-octanol/water)</u> (October 7, 2013) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 129/2013; 36 pages with a 4-page Confidential Appendix.</p> <p><i>US EPA Guideline: 830.7550, 830.7560, 830.7570</i></p>
	MRID Number: 49829512

	<p><u>Fipronil: Determination of the Water Solubility</u> (October 4, 2013) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 128/2013; 31 pages with a 4-page Confidential Appendix.</p> <p><i>US EPA Guideline: 830.7840, 830.7869</i></p>
	MRID Number: 49829513
	<p><u>Fipronil: Determination of the Vapour Pressure</u> (October 7, 2013) by M. Pardo Martinez, ChemService S.r.l. Controlli e Ricerche; Study No. 130/2013; 34 pages with a 4-page Confidential Appendix.</p> <p><i>US EPA Guideline: 830.7950</i></p>
	MRID Number: 49829514
COMPANY CONTACT:	<p>Ana Rodriguez-Koster Lewis & Harrison, LLC 122 C Street NW, Ste. 505 Washington, DC 20001</p> 



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number (Agent phone: 202-393-3903) Finchimica S.p.A., Via Lazio, 13, 25025 Manerbio (BS), Italy	EPA Registration Number/ File Symbol 53591-I
Active Ingredient(s) and/or representative test compound(s): Fipronil (CASRN 120068-37-3)	Date 2/13/2017
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Domestic Indoor	Product Name Fipronil Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 2/13/2017	Typed or Printed Name and Title Ana Rodriguez-Koster, Agent
---------------	--------------------------	---



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401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date February 13, 2017		EPA Reg. No./File Symbol 53591-I		Page 1 of 6	
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy		Product Fipronil Technical			
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)					
Deline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY					
830.1550	Product Identity and Composition	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1600	Description of the Materials Used to Produce the Product	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1620	Description of the Production Process	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1650	Description of the Formulation Process	Not Required	---	---	Footnote 1
830.1670	Discussion of Formation of Impurities	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1700	Preliminary Analysis	49829502 49829503	FINCHIMICA (Co.# 53591)	OWN	---
830.1750	Certified Limits	See CSF	---	---	---
830.1800	Enforcement Analytical Method	49829504 49829505	FINCHIMICA (Co.# 53591)	OWN	---
830.6302	Color	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6303	Physical State	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6304	Odor	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6313	Stability to Sunlight, Normal & Elevated Temperatures, Metals & Metal Ions	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6314	Oxidation/Reduction: Chemical Compatibility	49829508	---	---	Not Required ²
830.6315	Flammability	49829508	---	---	Not Required ³
830.6316	Explosibility	49829508	---	---	Not Required ⁴
830.6317	Storage Stability	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6319	Miscibility	49829508	---	---	Not Required ⁵
830.6320	Corrosion Characteristics	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6321	Dielectric Breakdown Voltage	49829508	---	---	Not Required ⁶
830.7000	pH	49829508	---	---	Not Required ⁷
830.7100	Viscosity	49829508	---	---	Not Required ³
830.7050	UV Visible Adsorption	49829509	FINCHIMICA (Co.# 53591)	OWN	---
830.7200	Melting Point	49829510	FINCHIMICA (Co.# 53591)	OWN	---
830.7220	Boiling Point	49829508	---	---	Not Required ³
830.7300	Density/Relative Density/Bulk Density	49829511	FINCHIMICA (Co.# 53591)	OWN	---
830.7370	Dissociation Constant	49829508	---	---	Not Required ⁸
830.7520	Particle Size, Fiber Length, and Diameter Distribution	49829508	---	---	Not Required ⁹

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

2/13/2017

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date February 13, 2017		EPA Reg. No./File Symbol 53591-I		Page 2 of 6	
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy		Product Fipronil Technical			
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7550/7560/7570	Partition Coefficient	49829512	FINCHIMICA (Co.# 53591)	OWN	---
830.7840/7869	Solubility	49829513	FINCHIMICA (Co.# 53591)	OWN	---
830.7950	Vapor Pressure	49829514	FINCHIMICA (Co.# 53591)	OWN	---
ENVIRONMENTAL FATE					
835.1230	Aged Column Leaching	42918664	BAYER (Co.# 264)	OLD	---
835.2120	Hydrolysis	42977905	BAYER (Co.# 264)	OLD	---
835.2120	Hydrolysis of Parent and Degradates as a Function of pH at 25°C	Not Applicable	---	---	Footnote 10
835.2240	Aqueous Photolysis	42918661	BAYER (Co.# 264)	OLD	---
835.2240	Direct Photolysis Rate of Parent and Degradates in Water	Not Applicable	---	---	Footnote 10
835.2410	Soil Photolysis	42918662	BAYER (Co.# 264)	OLD	---
835.4100	Aerobic Soil Metabolism	42918663	BAYER (Co.# 264)	OLD	---
		44262830	BAYER (Co.# 264)	OLD	---
835.4100	Aerobic Soil Metabolism - Degradates	Not Applicable	---	---	Footnote 10
835.4300	Aerobic Aquatic Metabolism	43291704	BAYER (Co.# 264)	OLD	---
		44261909	BAYER (Co.# 264)	OLD	---
835.4300	Aerobic Aquatic Metabolism - Degradates	Not Applicable	---	---	Footnote 10
835.4400	Anaerobic Aquatic Metabolism	43291704	BAYER (Co.# 264)	OLD	---
835.4400	Anaerobic Aquatic Metabolism - Degradates	Not Applicable	---	---	Footnote 10
835.6100	Terrestrial Field Dissipation - Soil	43291705	BAYER (Co.# 264)	OLD	---
ECOLOGICAL EFFECTS					
850.1010	Acute Aquatic Invertebrate Toxicity - Daphnia	42918625	BAYER (Co.# 264)	OLD	---
		42918669	BAYER (Co.# 264)	OLD	---
		42918671	BAYER (Co.# 264)	OLD	---
		43291719	BAYER (Co.# 264)	OLD	---
850.1025	Acute toxicity Estuarine and Marine Organisms - Oyster	43279701	BAYER (Co.# 264)	OLD	---
		43291701	BAYER (Co.# 264)	OLD	---
		43291702	BAYER (Co.# 264)	OLD	---
		45029601	BAYER (Co.# 264)	OLD	---
		45120001	BAYER (Co.# 264)	OLD	---
		45156301	BAYER (Co.# 264)	OLD	---
		45156302	BAYER (Co.# 264)	OLD	---

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

2/13/2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date February 13, 2017		EPA Reg. No./File Symbol 53591-I		Page 3 of 6	
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy		Product Fipronil Technical			
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1075	Fish Acute Toxicity – Bluegill Sunfish	42918624 43279702 42918674	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD	---
850.1075	Fish Acute Toxicity – Rainbow Trout	42918673 42977902 43279703 43291718	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD	---
850.1075	Fish Acute Toxicity – Degradates	Not Applicable	---	---	Footnote 10
850.1300	Daphnid Chronic Toxicity Test	42918626 43291723 43279704 44812801	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD	---
850.1300	Daphnid Chronic Toxicity Test – Degradates	Not Applicable	---	---	Footnote 10
850.1350	Fish Chronic Toxicity	43681201 45259202 45259203 44605502	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD	---
850.1400	Fish Early Life Stage Toxicity Test	Not Applicable	---	---	Footnote 10
850.1400	Fish Early Life Stage Toxicity Test – Degradates	45265101	BAYER (Co.# 264)	OLD	---
850.1500	Fish Life Cycle Toxicity Test	Not Applicable	---	---	Footnote 10
850.1500	Fish Life Cycle Toxicity Test – Degradates	43291707 43291707 44298002	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD	---
850.1730	Bioaccumulation in Fish	Not Applicable	---	---	Footnote 10
850.1730	Bioaccumulation in Fish – Degradates	Not Applicable	---	---	Footnote 10
850.1735	Whole Sediment Acute Freshwater Invertebrates – Midge (Two Additional Species; Parent & Degradates)	Not Applicable	---	---	Footnote 10
850.2100	Avian Acute Oral Toxicity Test (Fipronil, MB45613)	42918613 42918614 42918615 42918616 42918617	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD	---

Signature 	Name and Title: Ana Rodriguez-Koster, Agent	Date 2/13/2017
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DATA MATRIX

Date February 13, 2017		EPA Reg. No./File Symbol 53591-I		Page 4 of 6	
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy		Product Fipronil Technical			
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		42918618 42919619 43776601 43776602	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD	
850.2100	Avian Acute Oral Toxicity Test (Remaining Degradates)	Not Applicable	---	---	Footnote 10
850.2200	Avian Dietary Toxicity	42918620 42918621 44890301 44890302 44920701 45259201	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD OLD	---
850.2300	Avian Reproduction Test – Parent	42918622 49151522 42918623	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD	---
850.2300	Avian Reproduction Test – Degradates	Not Applicable	---	---	Footnote 10
850.3020	Honey Bee Acute Contact Toxicity – Parent & Degradates	Not Applicable	---	---	Footnote 10
850.3030	Honey Bee Toxicity of Residues on Foliage – Parent & Degradates	Not Applicable	---	---	Footnote 10
850.3040	Field Testing for Pollinators – Parent Only	Not Applicable	---	---	Footnote 10
850.4100	Aquatic Plant Toxicity – Seedling Emergence – Parent Only	Not Applicable	---	---	Footnote 10
850.4400	Aquatic Plant Growth (Algal and Aquatic Vascular Plant) – Parent & MB46513	42918656 42918657 42918658 42918659 42918660 43279705	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD OLD	---
850.4400	Aquatic Plant Growth (Algal and Aquatic Vascular Plant) – Remaining Degradates	Not Applicable	---	---	Footnote 10
850.5400	Algal Toxicity Tiers I and II – Degradates	Not Applicable	---	---	Footnote 10
RESIDUE CHEMISTRY – FOOD USES					
860.1200	Directions for Use	Not Applicable	---	---	Footnote 10

Signature 	Name and Title: Ana Rodriguez-Koster, Agent	Date 2/13/2017
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DATA MATRIX

Date February 13, 2017	EPA Reg. No./File Symbol 53591-I	Page 5 of 6
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	

Ingredient(s): **Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Crop Field Trial – Rice, Grain	Not Applicable	---	---	Footnote 10
TOXICOLOGY					
870.1100	Acute Oral Toxicity	42918628	BAYER (Co.# 264)	OLD	---
870.1200	Acute Dermal Toxicity	42918629 42918630	BAYER (Co.# 264)	OLD	---
870.1300	Acute Inhalation Toxicity	43544401	BAYER (Co.# 264)	OLD	---
870.2400	Primary Eye Irritation	42918632	BAYER (Co.# 264)	OLD	---
870.2500	Primary Dermal Irritation	42918633	BAYER (Co.# 264)	OLD	---
870.2600	Skin Sensitization	42918634	BAYER (Co.# 264)	OLD	---
870.3250	90-Day Dermal Toxicity (TGAI & EP)	49565601 49565602	BASF CORPORATION (Co.# 7969) BASF CORPORATION (Co.# 7969)	PAY PAY	---
870.3465	90-Day Inhalation Toxicity (TGAI & EP)	49602001	FIPRONIL TF - PET CLUSTER (Co.# 90573)	PAY	---
870.3700a	Developmental Toxicity – Rat	42977903	BAYER (Co.# 264)	OLD	---
870.3700b	Developmental Toxicity – Rabbit	42918646	BAYER (Co.# 264)	OLD	---
870.3800	Reproduction and Fertility Effects – Rat	42918647	BAYER (Co.# 264)	OLD	---
870.4100a	Chronic Toxicity – Rodent	42918648	BAYER (Co.# 264)	OLD	---
870.4100b	Chronic Toxicity – Dog	42918645	BAYER (Co.# 264)	OLD	---
870.4200	Carcinogenicity – Rat	42918648	BAYER (Co.# 264)	OLD	---
870.4200	Carcinogenicity – Mouse	42918649	BAYER (Co.# 264)	OLD	---
870.5100	Gene Mutation – Bacterial Revers Mutation	42918652	BAYER (Co.# 264)	OLD	---
870.5300	Gene Mutation – <i>In Vitro</i> Mammalian Cell Assay	42918651	BAYER (Co.# 264)	OLD	---
870.5375	Gene Mutation – Cytogenetics	42918653	BAYER (Co.# 264)	OLD	---
870.5395	<i>In Vivo</i> Cytogenetics	43680801	BAYER (Co.# 264)	OLD	---
870.6200a	Acute Neurotoxicity	42918635 44431801	BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD	---
870.6200b	Subchronic Neurotoxicity	43291703	BAYER (Co.# 264)	OLD	---
870.6300	Developmental Neurotoxicity	44501102 44501103 44500402	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD	---
870.7485	Metabolism and Pharmacokinetics	42918655 43253701	BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD	---
870.7600	Dermal Penetration – Rat	43737308	BAYER (Co.# 264)	OLD	---

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

2/13/2017



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DATA MATRIX

Date February 13, 2017		EPA Reg. No./File Symbol 53591-I		Page 6 of 6	
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy		Product Fipronil Technical			
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.7800	Immunotoxicity	49199503	BASF CORPORATION (Co.# 7969)	PAY	---
N/A	Comparative Thyroid Assay	49800601	FIPRONIL TF-CROP CLUSTER (Co.# 90575)	PAY	---
		49800602	FIPRONIL TF-CROP CLUSTER (Co.# 90575)	PAY	---
SPECIAL STUDIES					
SS-1066	Chronic Sediment, Hyalella Azteca – Parent & Degradates	Not Applicable	---	---	Footnote 10
SS-1069	Chronic Sediment, Chironomus dilutus – Parent & Degradates	Not Applicable	---	---	Footnote 10
SS-1072	Chronic Sediment, Leptocheirus plumulosus – Parent & Degradates	Not Applicable	---	---	Footnote 10

FOOTNOTES:

1. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not an end-use product.
2. These data are *not required* for FIPRONIL TECHNICAL given that the product does not contain any oxidizing or reducing agents. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
3. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not a liquid. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
4. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a solid and does not contain any combustible liquids. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
5. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not an emulsifiable liquid and is not to be diluted with petroleum solvents. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
6. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not intended for use in or around electrical outlets. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
7. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a poorly soluble substance in water. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
8. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL does not contain an acid or base functionality. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
9. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a poorly soluble substance in water, but not completely insoluble in water therefore partition coefficient data are not applicable.
10. FIPRONIL TECHNICAL is limited to the formulation of insecticides to be used for companion animal treatments. Per communications with Garland Waleko, USEPA CRM for Fipronil, this data requirement is not applicable to products that are strictly for use in companion animal treatments.

Signature 	Name and Title: Ana Rodriguez-Koster, Agent	Date 2/13/2017
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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number (Agent phone: 202-393-3903) Finchimica S.p.A., Via Lazio, 13, 25025 Manerbio (BS), Italy	EPA Registration Number/ File Symbol 53591-I
Active Ingredient(s) and/or representative test compound(s): Fipronil (CASRN 120068-37-3)	Date 1/31/2017
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Domestic Indoor	Product Name Fipronil Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ana Rodriguez-Koster</i>	Date 1/31/2017	Typed or Printed Name and Title Ana Rodriguez-Koster, Agent
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DATA MATRIX

Date January 31, 2017	EPA Reg. No./File Symbol 53591-I	Page 1 of 6
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	

Ingredient(s): **Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY					
830.1550	Product Identity and Composition	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1600	Description of the Materials Used to Produce the Product	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1620	Description of the Production Process	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1650	Description of the Formulation Process	Not Required	---	---	Footnote 1
830.1670	Discussion of Formation of Impurities	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1700	Preliminary Analysis	49829502 49829503	FINCHIMICA (Co.# 53591)	OWN	---
830.1750	Certified Limits	See CSF	---	---	---
830.1800	Enforcement Analytical Method	49829504 49829505	FINCHIMICA (Co.# 53591)	OWN	---
830.6302	Color	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6303	Physical State	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6304	Odor	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6313	Stability to Sunlight, Normal & Elevated Temperatures, Metals & Metal Ions	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6314	Oxidation/Reduction: Chemical Compatibility	49829508	---	---	Not Required ²
830.6315	Flammability	49829508	---	---	Not Required ³
830.6316	Explosibility	49829508	---	---	Not Required ⁴
830.6317	Storage Stability	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6319	Miscibility	49829508	---	---	Not Required ⁵
830.6320	Corrosion Characteristics	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6321	Dielectric Breakdown Voltage	49829508	---	---	Not Required ⁶
830.7000	pH	49829508	---	---	Not Required ⁷
830.7100	Viscosity	49829508	---	---	Not Required ⁸
830.7050	UV Visible Adsorption	49829509	FINCHIMICA (Co.# 53591)	OWN	---
830.7200	Melting Point	49829510	FINCHIMICA (Co.# 53591)	OWN	---
830.7220	Boiling Point	49829508	---	---	Not Required ⁹
830.7300	Density/Relative Density/Bulk Density	49829511	FINCHIMICA (Co.# 53591)	OWN	---
830.7370	Dissociation Constant	49829508	---	---	Not Required ¹⁰
830.7520	Particle Size, Fiber Length, and Diameter Distribution	49829508	---	---	Not Required ¹¹

Signature 	Name and Title: Ana Rodriguez-Koster, Agent	Date 1/31/2017
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DATA MATRIX

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Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	

Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7550/7560/7570	Partition Coefficient	49829512	FINCHIMICA (Co.# 53591)	OWN	---
830.7840/7869	Solubility	49829513	FINCHIMICA (Co.# 53591)	OWN	---
830.7950	Vapor Pressure	49829514	FINCHIMICA (Co.# 53591)	OWN	---
ENVIRONMENTAL FATE					
835.1230	Aged Column Leaching	42918664	BAYER (Co.# 264)	OLD	---
835.2120	Hydrolysis	42977905	BAYER (Co.# 264)	OLD	---
835.2120	Hydrolysis of Parent and Degradates as a Function of pH at 25°C	Not Applicable	---	---	Footnote 10
835.2240	Aqueous Photolysis	42918661	BAYER (Co.# 264)	OLD	---
835.2240	Direct Photolysis Rate of Parent and Degradates in Water	Not Applicable	---	---	Footnote 10
835.2410	Soil Photolysis	42918662	BAYER (Co.# 264)	OLD	---
835.4100	Aerobic Soil Metabolism	42918663	BAYER (Co.# 264)	OLD	---
		44262830	BAYER (Co.# 264)	OLD	---
835.4100	Aerobic Soil Metabolism - Degradates	Not Applicable	---	---	Footnote 10
835.4300	Aerobic Aquatic Metabolism	43291704	BAYER (Co.# 264)	OLD	---
835.4300	Aerobic Aquatic Metabolism - Degradates	Not Applicable	---	---	Footnote 10
835.4400	Anaerobic Aquatic Metabolism	44261909	BAYER (Co.# 264)	OLD	---
835.4400	Anaerobic Aquatic Metabolism - Degradates	Not Applicable	---	---	Footnote 10
835.6100	Terrestrial Field Dissipation - Soil	43291705	BAYER (Co.# 264)	OLD	---
ECOLOGICAL EFFECTS					
850.1010	Acute Aquatic Invertebrate Toxicity - Daphnia	42918625	BAYER (Co.# 264)	OLD	---
		42918669	BAYER (Co.# 264)	OLD	---
		42918671	BAYER (Co.# 264)	OLD	---
		43291719	BAYER (Co.# 264)	OLD	---
850.1025	Acute toxicity Estuarine and Marine Organisms - Oyster	43279701	BAYER (Co.# 264)	OLD	---
		43291701	BAYER (Co.# 264)	OLD	---
		43291702	BAYER (Co.# 264)	OLD	---
		45029601	BAYER (Co.# 264)	OLD	---
		45120001	BAYER (Co.# 264)	OLD	---
		45156301	BAYER (Co.# 264)	OLD	---
		45156302	BAYER (Co.# 264)	OLD	---
850.1075	Fish Acute Toxicity - Bluegill Sunfish	42918624	BAYER (Co.# 264)	OLD	---

Signature 	Name and Title: Ana Rodriguez-Koster, Agent	Date 1/31/2017
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DATA MATRIX

Date January 31, 2017		EPA Reg. No./File Symbol 53591-I		Page 3 of 6	
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy		Product Fipronil Technical			
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		43279702	BAYER (Co.# 264)	OLD	
850.1075	Fish Acute Toxicity – Rainbow Trout	42918673 42918674 42977902 43279703 43291718	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD	---
850.1075	Fish Acute Toxicity – Degradates	Not Applicable	---	---	Footnote 10
850.1300	Daphnid Chronic Toxicity Test	42918626 43279704 44812801	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD	---
850.1300	Daphnid Chronic Toxicity Test – Degradates	Not Applicable	---	---	Footnote 10
850.1350	Fish Chronic Toxicity	42818627 43681201 45259202 45259203	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD	---
850.1400	Fish Early Life Stage Toxicity Test	44605502	BAYER (Co.# 264)	OLD	---
850.1400	Fish Early Life Stage Toxicity Test – Degradates	Not Applicable	---	---	Footnote 10
850.1500	Fish Life Cycle Toxicity Test	45265101	BAYER (Co.# 264)	OLD	---
850.1500	Fish Life Cycle Toxicity Test – Degradates	Not Applicable	---	---	Footnote 10
850.1730	Bioaccumulation in Fish	43291707	BAYER (Co.# 264)	OLD	---
850.1730	Bioaccumulation in Fish – Degradates	Not Applicable	---	---	Footnote 10
850.1735	Whole Sediment Acute Freshwater Invertebrates – Midge (Two Additional Species; Parent & Degradates)	Not Applicable	---	---	Footnote 10
850.2100	Avian Acute Oral Toxicity Test (Fipronil, MB45613)	42918613 42918614 42918615 42918616 42918617 42918618 42919619 43776601 43776602	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD OLD OLD OLD OLD	---
850.2100	Avian Acute Oral Toxicity Test (Remaining)	Not Applicable	---	---	Footnote 10

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

1/31/2017



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DATA MATRIX

Date January 31, 2017	EPA Reg. No./File Symbol 53591-I	Page 4 of 6
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Degradates)				
850.2200	Avian Dietary Toxicity	42918620 42918621 44890301 44890302 44920701 45259201	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD OLD	---
850.2300	Avian Reproduction Test – Parent	42918622 42918623	BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD	---
850.2300	Avian Reproduction Test – Degradates	Not Applicable	---	---	Footnote 10
850.3020	Honey Bee Acute Contact Toxicity – Parent & Degradates	Not Applicable	---	---	Footnote 10
850.3030	Honey Bee Toxicity of Residues on Foliage – Parent & Degradates	Not Applicable	---	---	Footnote 10
850.3040	Field Testing for Pollinators – Parent Only	Not Applicable	---	---	Footnote 10
850.4100	Aquatic Plant Toxicity – Seedling Emergence – Parent Only	Not Applicable	---	---	Footnote 10
850.4400	Aquatic Plant Growth (Algal and Aquatic Vascular Plant) – Parent & MB46513	42918656 42918657 42918658 42918659 42918660 43279705	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD OLD	---
850.4400	Aquatic Plant Growth (Algal and Aquatic Vascular Plant) – Remaining Degradates	Not Applicable	---	---	Footnote 10
850.5400	Algal Toxicity Tiers I and II – Degradates	Not Applicable	---	---	Footnote 10
RESIDUE CHEMISTRY – FOOD USES					
860.1200	Directions for Use	Not Applicable	---	---	Footnote 10
860.1500	Crop Field Trial – Rice, Grain	Not Applicable	---	---	Footnote 10
TOXICOLOGY					
870.1100	Acute Oral Toxicity	42918628	BAYER (Co.# 264)	OLD	---
870.1200	Acute Dermal Toxicity	42918629 42918630	BAYER (Co.# 264)	OLD	---
870.1300	Acute Inhalation Toxicity	43544401	BAYER (Co.# 264)	OLD	---

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

1/31/2017

8/21/17



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DATA MATRIX

Date January 31, 2017	EPA Reg. No./File Symbol 53591-I	Page 5 of 6
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation	42918632	BAYER (Co.# 264)	OLD	---
870.2500	Primary Dermal Irritation	42918633	BAYER (Co.# 264)	OLD	---
870.2600	Skin Sensitization	42918634	BAYER (Co.# 264)	OLD	---
870.3250	90-Day Dermal Toxicity (TGAI & EP)	49565601	BASF CORPORATION (Co.# 7969)	PAY	---
		49565602	BASF CORPORATION (Co.# 7969)	PAY	---
870.3465	90-Day Inhalation Toxicity (TGAI & EP)	49602001	FIPRONIL TF - PET CLUSTER (Co.# 90573)	PAY	---
870.3700a	Developmental Toxicity - Rat	42977903	BAYER (Co.# 264)	OLD	---
870.3700b	Developmental Toxicity - Rabbit	42918646	BAYER (Co.# 264)	OLD	---
870.3800	Reproduction and Fertility Effects - Rat	42918647	BAYER (Co.# 264)	OLD	---
870.4100a	Chronic Toxicity - Rodent	42918648	BAYER (Co.# 264)	OLD	---
870.4100b	Chronic Toxicity - Dog	42918645	BAYER (Co.# 264)	OLD	---
870.4200	Carcinogenicity - Rat	42918648	BAYER (Co.# 264)	OLD	---
870.4200	Carcinogenicity - Mouse	42918649	BAYER (Co.# 264)	OLD	---
870.5100	Gene Mutation - Bacterial Revers Mutation	42918652	BAYER (Co.# 264)	OLD	---
870.5300	Gene Mutation - <i>In Vitro</i> Mammalian Cell Assay	42918651	BAYER (Co.# 264)	OLD	---
870.5375	Gene Mutation - Cytogenetics	42918653	BAYER (Co.# 264)	OLD	---
870.5395	<i>In Vivo</i> Cytogenetics	43680801	BAYER (Co.# 264)	OLD	---
870.6200a	Acute Neurotoxicity	42918635	BAYER (Co.# 264)	OLD	---
		44431801	BAYER (Co.# 264)	OLD	---
870.6200b	Subchronic Neurotoxicity	43291703	BAYER (Co.# 264)	OLD	---
870.6300	Developmental Neurotoxicity	44390002	BAYER (Co.# 264)	OLD	---
		44501102	BAYER (Co.# 264)	OLD	---
		44501103	BAYER (Co.# 264)	OLD	---
870.7485	Metabolism and Pharmacokinetics	42918655	BAYER (Co.# 264)	OLD	---
		43253701	BAYER (Co.# 264)	OLD	---
870.7600	Dermal Penetration - Rat	43737308	BAYER (Co.# 264)	OLD	---
870.7800	Immunotoxicity	49199503	BASF CORPORATION (Co.# 7969)	PAY	---
N/A	Comparative Thyroid Assay	49800601	FIPRONIL TF-CROP CLUSTER (Co.# 90575)	PAY	---
		49800602	FIPRONIL TF-CROP CLUSTER (Co.# 90575)	PAY	---

SPECIAL STUDIES

SS-1066	Chronic Sediment, <i>Hyaella Azteca</i> - Parent & Degradates	Not Applicable	---	---	Footnote 10
SS-1069	Chronic Sediment, <i>Chironomus dilutus</i> - Parent &	Not Applicable	---	---	Footnote 10

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

1/31/2017



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DATA MATRIX

Date January 31, 2017		EPA Reg. No./File Symbol 53591-I		Page 6 of 6	
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy		Product Fipronil Technical			
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Degradates				
SS-1072	Chronic Sediment, <i>Leptocheirus plumulosus</i> – Parent & Degradates	Not Applicable	---	---	Footnote 10

FOOTNOTES:

1. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not an end-use product.
2. These data are *not required* for FIPRONIL TECHNICAL given that the product does not contain any oxidizing or reducing agents.
3. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not a liquid.
4. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a solid and does not contain any combustible liquids.
5. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not an emulsifiable liquid and is not to be diluted with petroleum solvents.
6. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not intended for use in or around electrical outlets.
7. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a poorly soluble substance in water.
8. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL does not contain an acid or base functionality.
9. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a poorly soluble substance in water, but not completely insoluble in water therefore partition coefficient data are not applicable.
10. FIPRONIL TECHNICAL is limited to the formulation of insecticides/miticides to be used for companion animal treatments. Per communications with Garland Waleko, USEPA CRM for Fipronil, this data requirement is not applicable to products that are strictly for use in companion animal treatments.

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

1/31/2017



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number (Agent phone: 202-393-3903) Finchimica S.p.A., Via Lazio, 13, 25025 Manerbio (BS), Italy	EPA Registration Number/ File Symbol 53591-
Active Ingredient(s) and/or representative test compound(s): Fipronil (CASRN 120068-37-3)	Date 3/10/2016
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Non-Food Crop, Indoor, Domestic Outdoor or Indoor	Product Name Fipronil Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ana Rodriguez-Koster</i>	Date 3/10/2016	Typed or Printed Name and Title Ana Rodriguez-Koster, Agent
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DATA MATRIX

Date March 10, 2016	EPA Reg. No./File Symbol 53591-	Page 1 of 7
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT CHEMISTRY					
830.1550	Product Identity and Composition	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1600	Description of the Materials Used to Produce the Product	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1620	Description of the Production Process	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1650	Description of the Formulation Process	Not Required	---	---	Footnote 1
830.1670	Discussion of Formation of Impurities	49829501	FINCHIMICA (Co.# 53591)	OWN	---
830.1700	Preliminary Analysis	49829502 49829503	FINCHIMICA (Co.# 53591)	OWN	---
830.1750	Certified Limits	See CSF	---	---	---
830.1800	Enforcement Analytical Method	49829504 49829505	FINCHIMICA (Co.# 53591)	OWN	---
830.6302	Color	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6303	Physical State	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6304	Odor	49829506	FINCHIMICA (Co.# 53591)	OWN	---
830.6313	Stability to Sunlight, Normal & Elevated Temperatures, Metals & Metal Ions	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6314	Oxidation/Reduction: Chemical Compatibility	49829508	---	---	Not Required ²
830.6315	Flammability	49829508	---	---	Not Required ³
830.6316	Explosibility	49829508	---	---	Not Required ⁴
830.6317	Storage Stability	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6319	Miscibility	49829508	---	---	Not Required ⁵
830.6320	Corrosion Characteristics	49829507	FINCHIMICA (Co.# 53591)	OWN	---
830.6321	Dielectric Breakdown Voltage	49829508	---	---	Not Required ⁶
830.7000	pH	49829508	---	---	Not Required ⁷
830.7100	Viscosity	49829508	---	---	Not Required ³
830.7050	UV Visible Adsorption	49829509	FINCHIMICA (Co.# 53591)	OWN	---
830.7200	Melting Point	49829510	FINCHIMICA (Co.# 53591)	OWN	---
830.7220	Boiling Point	49829508	---	---	Not Required ³
830.7300	Density/Relative Density/Bulk Density	49829511	FINCHIMICA (Co.# 53591)	OWN	---
830.7370	Dissociation Constant	49829508	---	---	Not Required ⁸
830.7520	Particle Size, Fiber Length, and Diameter Distribution	49829508	---	---	Not Required ⁹

Signature <i>Ana Rodriguez-Koster</i>	Name and Title: Ana Rodriguez-Koster, Agent	Date 3/10/2016
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Handwritten:
matrix data
1/31/16



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DATA MATRIX

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Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7550/7560/7570	Partition Coefficient	49829512	FINCHIMICA (Co.# 53591)	OWN	---
830.7840/7869	Solubility	49829513	FINCHIMICA (Co.# 53591)	OWN	---
830.7950	Vapor Pressure	49829514	FINCHIMICA (Co.# 53591)	OWN	---
ENVIRONMENTAL FATE					
835.1230	Aged Column Leaching	42918664	BAYER (Co.# 264)	OLD	---
835.2120	Hydrolysis	42977905	BAYER (Co.# 264)	OLD	---
835.2121	Hydrolysis of Parent and Degradates as a Function of pH at 25°C	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
835.2240	Aqueous Photolysis	42918661	BAYER (Co.# 264)	OLD	---
835.2240	Direct Photolysis Rate of Parent and Degradates in Water	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
835.2410	Soil Photolysis	42918662	BAYER (Co.# 264)	OLD	---
835.4100	Aerobic Soil Metabolism	42918663	BAYER (Co.# 264)	OLD	---
		44262830	BAYER (Co.# 264)	OLD	---
835.4100	Aerobic Soil Metabolism – TEP	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
835.4300	Aerobic Aquatic Metabolism	43291704	BAYER (Co.# 264)	OLD	---
835.4300	Aerobic Aquatic Metabolism - Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
835.4400	Anaerobic Aquatic Metabolism	44261909	BAYER (Co.# 264)	OLD	---
835.4400	Anaerobic Aquatic Metabolism - Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
835.6100	Terrestrial Field Dissipation – Soil	43291705	BAYER (Co.# 264)	OLD	---

ECOLOGICAL EFFECTS

850.1010	Acute Aquatic Invertebrate Toxicity – Daphnia	42918625	BAYER (Co.# 264)	OLD	---
		42918669	BAYER (Co.# 264)	OLD	---
		42918671	BAYER (Co.# 264)	OLD	---
		43291719	BAYER (Co.# 264)	OLD	---
850.1025	Acute toxicity Estuarine and Marine Organisms - Oyster	43279701	BAYER (Co.# 264)	OLD	---
		43291701	BAYER (Co.# 264)	OLD	---
		43291702	BAYER (Co.# 264)	OLD	---
		45029601	BAYER (Co.# 264)	OLD	---
		45120001	BAYER (Co.# 264)	OLD	---
		45156301	BAYER (Co.# 264)	OLD	---
		45156302	BAYER (Co.# 264)	OLD	---
850.1075	Fish Acute Toxicity – Bluegill Sunfish	42918624	BAYER (Co.# 264)	OLD	---

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

3/10/2016



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DATA MATRIX

Date March 10, 2016	EPA Reg. No./File Symbol 53591-	Page 3 of 7
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		43279702	BAYER (Co.# 264)	OLD	
850.1075	Fish Acute Toxicity – Rainbow Trout	42918673 42918674 42977902 43279703 43291718	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD	---
850.1075	Fish Acute Toxicity – Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.1300	Daphnid Chronic Toxicity Test	42918626 43279704 44812801	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD	---
850.1300	Daphnid Chronic Toxicity Test – Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.1350	Fish Chronic Toxicity	42818627 43681201 45259202 45259203	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD	---
850.1400	Fish Early Life Stage Toxicity Test	44605502	BAYER (Co.# 264)	OLD	---
850.1400	Fish Early Life Stage Toxicity Test – Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.1500	Fish Life Cycle Toxicity Test	45265101	BAYER (Co.# 264)	OLD	---
850.1500	Fish Life Cycle Toxicity Test – Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.1730	Bioaccumulation in Fish	43291707	BAYER (Co.# 264)	OLD	---
850.1730	Bioaccumulation in Fish – Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.1735	Whole Sediment Acute Freshwater Invertebrates – Midge: MB45950 MB46136 MB46513 Fipronil	45084801 45175901 45375901 45878001	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD PAY	---
850.1735	Whole Sediment Acute Freshwater Invertebrates – Midge (Two Additional Species; Parent & Degradates)	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.2100	Avian Acute Oral Toxicity Test (Fipronil, MB45613)	42918613 42918614 42918615 42918616	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD	---

Signature 	Name and Title: Ana Rodriguez-Koster, Agent	Date 3/10/2016
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date March 10, 2016	EPA Reg. No./File Symbol 53591-___	Page 4 of 7
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		42918617 42918618 42919619 43776601 43776602	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD	
850.2100	Avian Acute Oral Toxicity Test (Remaining Degradates)	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.2200	Avian Dietary Toxicity	42918620 42918621 44890301 44890302 44920701 45259201	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD OLD	---
850.2300	Avian Reproduction Test – Parent	42918622 42918623	BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD	---
850.2300	Avian Reproduction Test – Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.3020	Honey Bee Acute Contact Toxicity – Parent & Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.3030	Honey Bee Toxicity of Residues on Foliage – Parent & Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.3040	Field Testing for Pollinators – Parent Only	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.4100	Aquatic Plant Toxicity – Seedling Emergence – Parent Only	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.4400	Aquatic Plant Growth (Algal and Aquatic Vascular Plant) – Parent & MB46513	42918656 42918657 42918658 42918659 42918660 43279705	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD OLD OLD OLD	---
850.4400	Aquatic Plant Growth (Algal and Aquatic Vascular Plant) – Remaining Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
850.5400	Algal Toxicity Tiers I and II – Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
RESIDUE CHEMISTRY – FOOD USES					
860.1200	Directions for Use	Not Applicable	---	---	Footnote 11

Signature

Ana Rodriguez-Koster

Name and Title:

Ana Rodriguez-Koster, Agent

Date

3/10/2016



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WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 10, 2016	EPA Reg. No./File Symbol 53591-	Page 5 of 7
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy	Product Fipronil Technical	
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1500	Crop Field Trial – Rice, Grain	Not Applicable	---	---	Footnote 11
TOXICOLOGY					
870.1100	Acute Oral Toxicity	42918628	BAYER (Co.# 264)	OLD	---
870.1200	Acute Dermal Toxicity	42918629 42918630	BAYER (Co.# 264)	OLD	---
870.1300	Acute Inhalation Toxicity	43544401	BAYER (Co.# 264)	OLD	---
870.2400	Primary Eye Irritation	42918632	BAYER (Co.# 264)	OLD	---
870.2500	Primary Dermal Irritation	42918633	BAYER (Co.# 264)	OLD	---
870.2600	Skin Sensitization	42918634	BAYER (Co.# 264)	OLD	---
870.3250	90-Day Dermal Toxicity (TGAI & EP)	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
870.3465	90-Day Inhalation Toxicity (TGAI & EP)	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
870.3700a	Developmental Toxicity – Rat	42977903	BAYER (Co.# 264)	OLD	---
870.3700b	Developmental Toxicity – Rabbit	42918646	BAYER (Co.# 264)	OLD	---
870.3800	Reproduction and Fertility Effects – Rat	42918647	BAYER (Co.# 264)	OLD	---
870.4100a	Chronic Toxicity – Rodent	42918648	BAYER (Co.# 264)	OLD	---
870.4100b	Chronic Toxicity – Dog	42918645	BAYER (Co.# 264)	OLD	---
870.4200	Carcinogenicity – Rat	42918648	BAYER (Co.# 264)	OLD	---
870.4200	Carcinogenicity – Mouse	42918649	BAYER (Co.# 264)	OLD	---
870.5100	Gene Mutation – Bacterial Revers Mutation	42918652	BAYER (Co.# 264)	OLD	---
870.5300	Gene Mutation – <i>In Vitro</i> Mammalian Cell Assay	42918651	BAYER (Co.# 264)	OLD	---
870.5375	Gene Mutation – Cytogenetics	42918653	BAYER (Co.# 264)	OLD	---
870.5395	<i>In Vivo</i> Cytogenetics	43680801	BAYER (Co.# 264)	OLD	---
870.6200a	Acute Neurotoxicity	42918635 44431801	BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD	---
870.6200b	Subchronic Neurotoxicity	43291703	BAYER (Co.# 264)	OLD	---
870.6300	Developmental Neurotoxicity	44390002 44501102 44501103	BAYER (Co.# 264) BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD OLD	---
870.7485	Metabolism and Pharmacokinetics	42918655 43253701	BAYER (Co.# 264) BAYER (Co.# 264)	OLD OLD	---
870.7600	Dermal Penetration – Rat	43737308	BAYER (Co.# 264)	OLD	---
870.7800	Immunotoxicity	To be Developed	SEE ATTACHMENT	PAY	Footnote 10

SPECIAL STUDIES

Signature 	Name and Title: Ana Rodriguez-Koster, Agent	Date 3/10/2016
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WASHINGTON, D.C. 20460

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DATA MATRIX

Date March 10, 2016		EPA Reg. No./File Symbol 53591-___		Page 6 of 7	
Applicant's/Registrant's Name & Address: Finchimica S.p.A. Via Lazio, 13, 25025 Manerbio (BS), Italy		Product Fipronil Technical			
Ingredient(s): Fipronil (EPA PC Code: 129121; CAS No. 120068-37-3)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
SS-1066	Chronic Sediment, Hyalella Azteca – Parent & Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
SS-1066	Chronic Sediment, Chironomus dilutus – Parent & Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10
SS-1072	Chronic Sediment, Leptocheirus plumulosus – Parent & Degradates	To be Developed	SEE ATTACHMENT	PAY	Footnote 10

FOOTNOTES:

1. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not an end-use product.
2. These data are *not required* for FIPRONIL TECHNICAL given that the product does not contain any oxidizing or reducing agents. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
3. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not a liquid. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
4. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a solid and does not contain any combustible liquids. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
5. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not an emulsifiable liquid and is not to be diluted with petroleum solvents. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
6. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is not intended for use in or around electrical outlets. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
7. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a poorly soluble substance in water. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
8. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL does not contain an acid or base functionality. With this submission, we are including a formal justification document that discusses in detail why these data requirements are not applicable to FIPRONIL TECHNICAL.
9. These data are *not required* for FIPRONIL TECHNICAL given that FIPRONIL TECHNICAL is a poorly soluble substance in water, but not completely insoluble in water therefore partition coefficient data are not applicable.
10. The Agency required development of these data as part of the Generic Data Call-In Notice Issued on 3/14/2015. To address this data requirement, Finchimica S.p.A. has made offers to cost share in the development of these data to all companies that were included in the Generic Data Call-In Notice for fipronil.
11. These data are *not required* for FIPRONIL TECHNICAL given that the label for FIPRONIL TECHNICAL does not include any food uses.

Signature 	Name and Title: Ana Rodriguez-Koster, Agent	Date 3/10/2016
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United States Environmental Protection Agency
Washington, D.C. 20460

OMB Approval 2070-0174

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: NA - Fipronil

DCI Number: GDC-129121-1305

Co. Nr.	Company Name	Agent For Company	Address	City	State	ZIP
88062	HORIZON VALLEY GENERICS, INC	PYXIS REGULATORY CONSULTING, INC	4110 136TH ST. NW	GIG HARBOR	WA	98332
87373	ARGITE, LLC	PYXIS REGULATORY CONSULTING, INC.	4110 1136TH STREET, NW	GIG HARBOR	WA	98332
432	BAYER ENVIRONMENTAL SCIENCE		2 T. W. ALEXANDER DRIVE, P. O. Box 12014	RESEARCH TRIANGLE PARK	NC	27709
87825	VIRBAC S.A.	EXPONENT, INC	1150 CONNECTICUT AVE. NW STE 1000	WASHINGTON	DC	20036
86223	NORBROOK LABORATORIES LIMITED	NORBROOK INC	9733 LOIRET BLVD	LENEXA	KS	66219
7999	BASF CORPORATION		26 DAVIS DRIVE, P.O. Box 13528	RESEARCH TRIANGLE PARK	NC	277090528
33658	GHARDA CHEMICALS LIMITED	IPM RESOURCES LLC	4032 CROOKERS LAKE BLVD. STE 818	SARASOTA	FL	34238
88802	PRODIGY TECHNICAL HOLDING, LLC	PYXIS REGULATORY CONSULTING INC	4110 136TH ST. NW	GIG HARBOR	WA	98332
2382	VIRBAC A.H. INC.	EXPONENT, INC.	1150 CONNECTICUT AVE NW, STE 1100	WASHINGTON	DC	20036
2598	THE HARTZ MOUNTAIN CORPORATION		400 PLAZA DRIVE	SECAUCUS	NJ	07094
74054	IRVITA PLANT PROTECTION N.V.	MAKHTESHIM-AGAN OF NORTH AMERICA INC	3120 HIGHWOODS BLVD., SUITE 100	RALEIGH	NC	27604
87180	ZHEJIANG HISUN PHARMACEUTICALS, CO. LTD	HISUN PHARMACEUTICALS USA, INC	212 CARNEGIE CENTER	PRINCETON	NJ	085408234
87831	RAYMAT MATERIALS INC.	J&T ASSOCIATES LLC	4081 NORTH 156TH DRIVE	GOODYEAR	AZ	85395

Fee for Service

W
{982714,~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 3

Receipt No.

S- 982714

EPA File Symbol/Reg. No.

53591-I

Pin-Punch Date:

3/10/2016

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R334

Granted: R334

Amount Due: \$ 19,838⁰⁰

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Xmmanly

Date: 3/14/16

Remarks:

DOCUMENTUM

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For your security, we recommend you close your browser when you complete your payment.

Payment Confirmation - Pesticide Registration Improvement Act - Prepayment

[Before You Begin](#) [1 Complete Agency Form](#) [2 Enter Payment Info](#) [3 Review & Submit](#) [4 Confirmation](#)

Payment Confirmation

Your payment is complete

Pay.gov Tracking ID: 25PP5A7K

Agency Tracking ID: 74953519528

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Bank account (ACH)

Payment Amount: \$19,838.00

Transaction Date: 02/04/2016 04:24:25 PM EST

Payment Date: 02/05/2016

Registration Number:

Company Name: Finchimica S.P.A.

Company Number: 53591

Action Code: R334

Account Information

Account Holder Name: Lewis & Harrison, LLC

Routing Number: 051400549

Account Number: *****8515

Email Confirmation Receipt

Confirmation Receipts have been emailed to

alkoster@lewisharrison.com

[Print Receipt](#)

Register today!

[Register Now](#)

or

[Log in](#)

Please consider registering for a Pay.gov account. With a Pay.gov account you can manage payments and view history.

WARNING WARNING WARNING

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Note: This system may contain Sensitive But Unclassified (SBU) data that requires specific data privacy handling.

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 Fiscal Service

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3/10/16

Experts In-Processing Signature: MP Date 3/15/16 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>53591-I</u>		EPA Receipt Date: <u>3/10/16</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			<input checked="" type="checkbox"/>		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			<input checked="" type="checkbox"/>		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>No inerts to review</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>		
	Certificate and data matrix consistent			<input checked="" type="checkbox"/>		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					<input checked="" type="checkbox"/>
5	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>		
	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	<input checked="" type="checkbox"/>				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			<input checked="" type="checkbox"/>		
7	Is the data package consistent with PR Notice 86-5			<input checked="" type="checkbox"/>		
8	Notice of Filing included with petitions					<input checked="" type="checkbox"/>

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

Comments:

Documentation:

- Application Form (tPA Form 8570-1) missing signature (Pass) / Fail
- emailed Ana Koster regarding deficiency 3/21/16
- received reply with correction 3/21/16
- Required forms are complete

Inerts:

No inerts to review (Pass) / Fail

PRN 11-3:

MRID: 498295

(PASS) / Fail

Overall Status:

(Pass) / Fail

SM 3/21/16

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Mattingly, Sean

From: Ana Koster <alkoster@lewisharrison.com>
Sent: Monday, March 21, 2016 1:02 PM
To: Mattingly, Sean
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Fipronil Technical (EPA Reg. No. 53591-I)
Attachments: 053591-xxxxx.20160310.FipronilTechnical.NewRegistration.AF.pdf

Hi Sean,

Thanks for your message and apologies for the oversight. Attached is the form with my signature. Let me know if you have any other question or if I can be of further assistance.

Best,

Ana Rodriguez-Koster
Senior Associate & Team Lead, Caribbean & Latin America
Lewis & Harrison, LLC
122 C Street NW, Suite 505
Washington, DC 20001
Home office phone#: 410-696-2236 (M, T, R, F)
Office phone#: 202-393-3903 x.117 (W)
f. 202-393-3906
alkoster@lewisharrison.com

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From: Mattingly, Sean [<mailto:Mattingly.Sean@epa.gov>]
Sent: Monday, March 21, 2016 12:57 PM
To: Ana Koster
Cc: Ashe, Anthony
Subject: Submission to EPA: Fipronil Technical (EPA Reg. No. 53591-I)

Dear Ms. Koster,

My name is Sean Mattingly and I am a contractor with the EPA. I am contacting you in regards to your submissions in support of the product Fipronil Technical (EPA Reg. No. 53591-I). We have found few deficiencies with the submissions that will need to be addressed:

1. Please provide the Application Form (EPA Form 8570-1) with your signature.

Please send the necessary documents before March 31st so that we may further process your submission. After March 31st, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Sean Mattingly

Contractor, US EPA
2777 S. Crystal Drive, S-4822
Arlington, VA 22202
703-347-0501
Email: mattingly.sean@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 15, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-514975
EPA File Symbol or Registration Number: 53591-I
Product Name: Fipronil Technical
EPA Receipt Date: 10-Mar-2016
EPA Company Number: 53591
Company Name: FINCHIMICA S.P.A.

ANA KOSTER
LEWIS & HARRISON, LLC
AGENT FOR: FINCHIMICA S.P.A.
122 C STREET, N.W., SUITE 505
WASHINGTON, DC 20001-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R334

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF
THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL
FORM;SELECTIVE DATA CITATION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff

Information Technology & Resources Management Division

